Dräger Medical

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# PRODUCT BULLETIN

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| **Product(s):** | Narkomed 2C, Narkomed 4, Narkomed GS, Narkomed 6000 |
| **Bulletin Number:** | 097 |
| **Release Date:** | 3/16/00 |
| **Pages:** | 8 |

## Subject: Performance of the Ultrasonic Flow Sensor

It has come to our attention that certain conditions of use, especially conditions of low flow, may affect the performance of the ultrasonic flow sensor. The purpose of this document is to make you aware of the performance issues being reported, and differentiate those issues that have been addressed through redesign and those related to customer usage.

### Performance Issues Reported

1. Breakage
2. Leakage
3. "Reverse flow" message
4. "VOL SENSOR DISC" message
5. "VOL SENS ERR" (applicable to NM 6000 only)
6. Erratic readings

### Engineering Redesign Issues

Engineering has implemented the following changes to improve performance relative to performance issues #1 - 3.

- To minimize breakage, the manufacturing process was improved by strengthening the bonds used in the flow sensor housing.
- To provide a better seal and eliminate leakage at the junction of the transducer and the transducer housing, an additional “O” ring was added to the base of the transducer, making a total of three.
- To eliminate noise detection in idle machines that would mimic flow and cause reverse flow alarms, the Narkomed flow sensor software was enhanced.

Any customers experiencing issues related to breakage, leakage, or reverse flow (under dry conditions of use) should contact Dräger Service or your local service representative regarding an upgrade.

Engineering has changed the part numbers of the redesigned flow sensor assemblies.

| | Original part number | Redesigned part number |
|---|---|---|
| Flow sensor assembly | 4113819 | 4115754 |
| Flow sensor assembly (SE) | | 4115777 (SE) |

## Customer Usage Issues

Depending on the conditions of use and the environment, condensation can accumulate in the flow sensor housing. Moderate amounts of condensation should not affect operation. Excessive condensation, however, can result in erratic volume data and/or VOL SENSOR DISC, VOL SENS ERR, or REVERSE FLOW alarms. Circumstances under which excessive condensation may occur include:

- Long procedures
- Using the anesthesia system in a very cold operating room environment
- Low fresh gas flow, in the range of 1 liter/min
- Beginning a case with moisture already in the flow sensor or connecting hoses; and
- Use of humidifiers

Frequent cleaning could increase the amount of residual moisture in the sensor if proper cleaning procedures are not followed. In addition, the increased handling could increase the likelihood of incorrect re-assembly or component damage. This can also trigger performance issues #3 - 6.

The following recommendations should reduce or eliminate the performance issues.

### *Recommendation #1- Proper technique for clearing of condensation and flow sensor reassembly*

Instructions for clearing condensation, as well as disassembly, cleaning, and reassembly of the flow sensor are attached.

The following points should be emphasized.

1. The tip of the transducer should be free of moisture droplets or a "VOL SENS DISC" or "VOL SENS ERR" alarm could occur.
2. The transducers should be rotated slightly as they are pressed into the housing for easier seating to ensure a tight seal.
3. The flow housing must be fully seated into the electronics housing and an audible click is heard when the transducer housing is inserted correctly. If the assembly doesn't click in place, the housing is seated improperly which could result in a "VOL SENS DISC " or "VOL SENS ERR" alarm. Erratic readings, with intermittent loss of volume numerics, could also occur with improper assembly of the housing.

4. If the transducer housing does not fit easily into the electronics housing, check to see that the flow housing is facing in the right direction. Do not try to force the transducer housing into the electronic housing or you may damage one or both of the housings.

***Recommendation #2- Daily maintenance***

When *conditions* that contribute to high levels of condensation in the flow sensor are present, customers are encouraged to drain the sensor housing and connection hose elements on the Narkomed 2C, 4, and GS at the end of the day (per attachment #1). Customers may also want to consider stocking spare flow sensor housings/transducers to facilitate maintenance.

***Recommendation #3- Use of Patient Filters/HME's***

The use of certain filters and HME's in the breathing circuit during a case has been shown to reduce moisture accumulation. In addition to reducing moisture carryover into the system, filters can contribute to improved infection control however; the effects of increased dead space, increased flow resistance, and added cost may need to be considered by the customer.

King Systems provides a series of products that could be used:

| | |
|---|---|
| AN003 | HME |
| MS102 | HME |
| MS111 | HME/filter |

Local King representatives can be contacted for samples for customer evaluation. A list of these representatives with contact information is attached. The customer, alternatively, can coordinate through their local distributor for filter samples and support.

If you have any questions or observations about the sensors, or any of the above topics, please contact Greg Sutherland at 800-462-7566 extension #2311.

***King Systems Corporation***
*Domestic Sales Representation*
*800-642-5464*

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| Customer Service | Sue Wesley 356 | Linda Pettit 325 | Mike Little 324 | Julie Roberts 326 | Sue Wesley 356 |
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| | | | | | Wanda Harrison NM 403 |

## Attachment 1 - Clearing Condensation

The following information specific to clearing condensation from the ultrasonic flow sensor has been copied from the Narkomed 2C, 4, GS, and 6000 Operator's Instruction Manuals, Routine Maintenance and Cleaning Section. Text marked with an asterisk (*) has been added for additional clarification.

Depending on the conditions of use and the environment, condensation can accumulate in the flow sensor housing. Moderate amounts of condensation should not affect operation. Excessive condensation can result in erratic volume data and/or VOL SENSOR DISC, VOL SENS ERR, or REVERSE FLOW alarms.

Circumstances under which excessive condensation may occur include:

- Long procedures
- Using the anesthesia system in a colder operating room environment
- Low fresh gas flow, in the range of 1 liter/min
- Beginning a case with moisture already in the flow sensor or connecting hoses
- Use of humidifiers

**Removing Moisture From the Ultrasonic Flow Sensor**

1. Remove the patient hose and connector hose from either side of the flow sensor and remove the sensor from the support bracket.
2. Press down on the lever under the flow housing and pull the flow housing/transducer assembly out of the electronics housing.
3. Pull both transducers out of the flow housing.
4. See Figure 1 below.

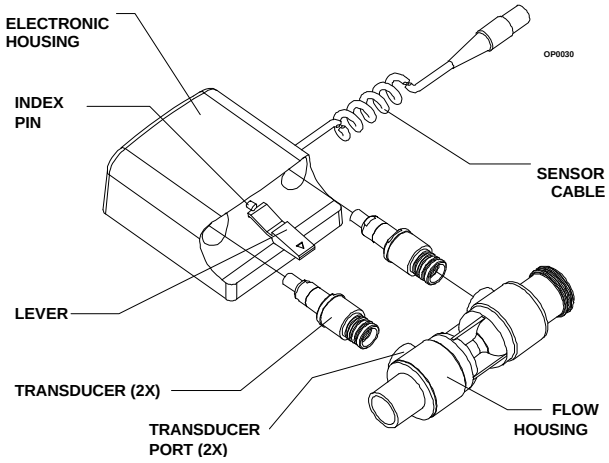


**Figure 1.**

**Removing Moisture From the Ultrasonic Flow Sensor (continued)**

5. Tip and shake the flow housing to release fluid trapped in the housing.
6. Make sure that all large droplets are cleared from the transducer ports of the flow housing.
7. * Check for any droplets on the black surface of the transducer head and in the surrounding groove.
8. Pat the transducer heads with a soft, lint-free cloth to remove any moisture.
9. Press the transducers back into their ports in the flow housing. Ensure that they are fully seated in the flow housing.

   **NOTE:** ***** The transducers may seat more easily if they are rotated slightly as they are pressed in.

10. Slide the electronics housing over the flow housing/transducer assembly. Be sure that the assembly clicks into place.

    **NOTE:** If the flow housing/transducer assembly does not fit easily into the electronics housing, make sure the flow housing is facing the right direction. Compare the direction to the illustration on the electronics housing. The index pin on the electronics housing should align with the hole in the flow housing.

    **NOTE:** * The transducers must be fully seated in the flow housing and the flow housing must be completely installed in the electronics housing with an audible click. Failure to properly reassemble the flow sensor may result in improper operation, to include VOL SENSOR DISC and REVERSE FLOW messages and erratic volume data.

11. Slide the flow sensor onto the bracket.
12. Connect the patient hose to the expiratory hose terminal on the flow sensor.
13. When connecting to the Narkomed 2C, 4 and GS products, drain any condensation from the connector hose assembly that connects the flow sensor and the expiratory valve. Reconnect the hose to the threaded connector on the flow housing and tighten.

## Attachment 2 - Disassembly, Cleaning and Reassembly

The following information specific to cleaning the ultrasonic flow sensor has been copied from the Narkomed 2C, 4, GS and 6000 Operator's Instruction Manual, Routine Maintenance and Cleaning Section. Text marked with an asterisk (*) has been added for additional clarification.

### Disassembling the Flow Housing/Transducer Assembly

1. Press down on the lever under the flow housing and pull the flow housing/transducer assembly out of the electronics housing.
2. Pull both transducers out of the flow housing.
3. See Figure 1 below.

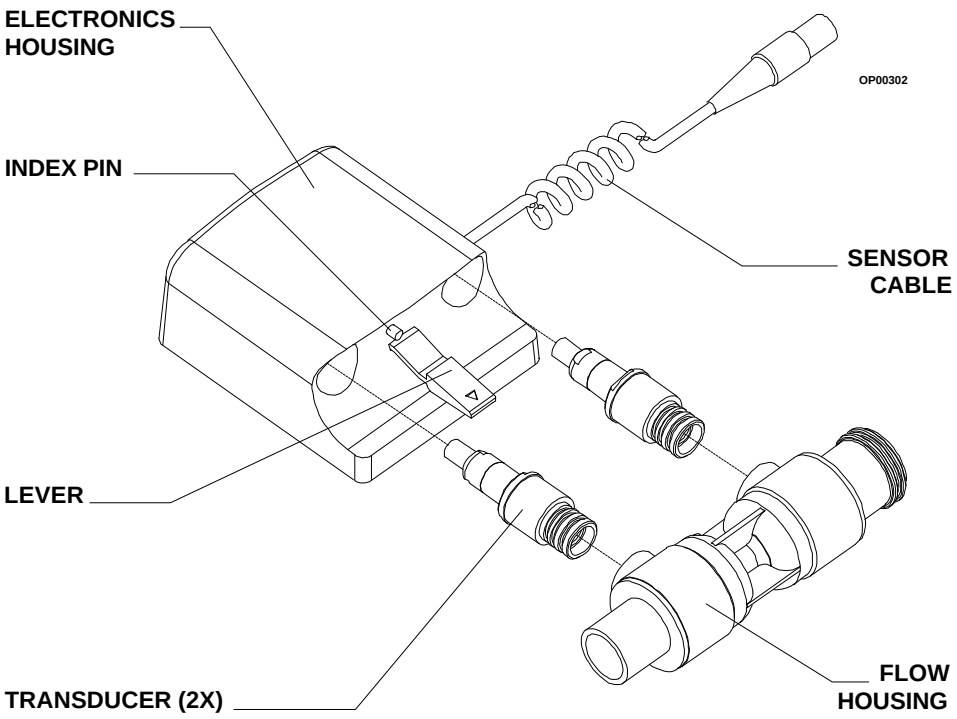


**Figure 1.**

**Cleaning and Disinfecting the Ultrasonic Flow Sensor Housing and Transducers**

1. Wash the flow housing and transducers with mild detergent and water. Follow with a distilled water rinse. These components can be immersed.
2. The flow housing and transducers can be autoclaved at a temperature not exceeding 121$^{o}$ C. Follow the manufacturer's instructions for the process. Allow the transducers to normalize for 30 minutes under room ambient conditions before using them.
3. Ensure all components are completely dry prior to reassembling the flow housing components of the sensor. Refer to the procedure on clearing condensation in Attachment 1.

**Cleaning and Disinfecting the Ultrasonic Flow Sensor *Electronics* Housing and Cable**

1. Wipe the electronics housing and sensor cable with a clean, soft cloth moistened with mild detergent water. Take care not to allow any fluid to access the interior of the electronics housing.
2. The electronics housing and sensor cable can be wiped with a clean, soft, lint-free cloth moistened with a 70% to 90% diluted solution of ethyl or isopropyl alcohol or sodium hypochlorite (5.2% household bleach) at 1:500 dilution (100 PPM chlorine).

   **NOTE:** Draeger Medical makes no claim about the efficacy of these agents or this method of cleaning for infection control. Consult your hospital's infection control officer or epidemiologist.

**Reassembling Parts after Cleaning and Disinfection**

1. Press the transducers back into their ports in the flow housing. Ensure that they are fully seated in the flow housing.

   **NOTE:** ***** The transducers may seat more easily if they are rotated slightly as they are pressed in.

2. Slide the electronics housing over the flow housing/transducer assembly. Be sure that the assembly clicks into place.

   **NOTE:** If the flow housing/transducer assembly does not fit easily into the electronics housing, make sure the flow housing is facing the right direction. Compare the direction to the illustration on the electronics housing. The index pin on the electronics housing should align with the hole in the flow housing.

   **NOTE:** * The transducers must be fully seated in the flow housing and the flow housing must be completely installed in the electronics housing with an audible click. Failure to properly reassemble the flow sensor may result in improper operation, to include VOL SENSOR DISC and REVERSE FLOW messages and erratic volume data.